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10/585,382	12/04/2007	Timothy G. Geiser	5275	2864

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EXAMINER
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HOBBS, MICHAEL L

ART UNIT	PAPER NUMBER
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1797

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08/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/585,382	<b>Applicant(s)</b> GEISER ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14, 15 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14, 15 and 36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment filed on 07/08/2010 has been considered and entered for the record.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Woudenberg et al. (US 6,126,899) as evidenced by Liu et al. (*Anal. Chem.* **2002**, 73, 4196-4201).

4. For claim 1, Woudenberg discloses the following limitations:

*"a substrate and an optically transparent cover"*: the reference discloses a substrate (substrate 32) and a transparent window or cover where this window is formed of various layers composed of either silica-based glasses, quartz, polycarbonate or an optically transparent plastic layer (col. 5 lines 44-46; col. 11 lines 14-18).

Regarding the structural limitations of the substrate:

*"a first surface"*: The substrate disclosed by Woudenberg includes a first surface as shown in Figure 1B.

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*"at least one sample receiving chamber"*: The applied reference includes a sample inlet (inlet 38a) or sample receiving chamber (col. 6 line 6).

*"at least one distributor channel in fluid communication with the [...] sample receiving chamber"*: A distribution network (network 34a) or channel(s) are disclosed by the reference (col. 6 lines 5-6).

*"at least one reaction chamber"*: There are a plurality of detection or reaction chambers (chamber 44a) that branch off the distribution channel (col. 6 lines 6-7) and with regards to the chambers comprising a *"a recess in the first surface"*, the chambers are present within the substrate and are being interpreted as forming a "recess" within the substrate.

*"at least one inflow channel"*: With regards to the inflow channel, the section of the single flow channel (channel 46a) between the inlet (inlet 38) and the first of the detection chambers (chambers 44a) as shown in Figure 1 is being interpreted as the inflow channel of the instant application.

*"at least one vent"*: Woudenberg discloses a vacuum port (port 40) is in fluid communication with the detection chambers (Fig. 1a) and is fully capable of functioning as a vent. In the alternative, the port can be connected to a three-way valve in order to expose the network to either a vacuum source and a vent (col. 9 lines 45-48).

5. Finally, regarding the substrate having a *"a glass transition temperature of greater than about 115°C"*, Woudenberg discloses that the substrate can be made from

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polycarbonate which has a glass transition temperature of 145°C (page 4147, col. 3 lines 5-7) which is greater than 115°C as evidenced by Liu.

6. With regards to claim 2, the channels of Woudenberg are fully capable of enabling the sample to be transported through the chamber by capillary action.

7. With regards to claims 3-6, the substrate of Woudenberg has the inherent property of having a thermal conductivity about or greater than 0.5 W/m°K, 1.0 W/m°K, 2.0 W/m°K and 5.0 W/m°K. Finally, this substrate is being interpreted as having a portion adjacent to the reaction well.

8. For claim 7, Woudenberg discloses a plurality of detection or reaction chambers (chambers 44a) as shown in Figure 1a.

9. For claim 8, Woudenberg discloses that the opacity or transparency of the substrate material defining the detection chambers will generally have an effect on the permissible detection geometries used for signal detection (col. 11 lines 39-41). To address this issue, Woudenberg uses an optically opaque lower wall and sides of the detection chamber (col. 11 lines 48-49) where this opaque material exhibits low reflectance in order to minimize the amount of light reflected back to the detector (col. 11 lines 54-56).

10. Therefore, Woudenberg meets the limitations of claims 1-8.

### ***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woudenberg et al. (US 6,126,899) in view of Gong et al. (US 2003/0138941 A1).

15. For claim 9 and 10, Woudenberg discloses a substrate made of silicon or polycarbonate (col. 10 lines 60-66) and discloses where the material selected facilitates rapid heating and cooling of the device (col. 10 line 54 – col. 11 line 1). Finally the substrate can be made from a plurality of materials (col. 11 lines 2-3), but differs from

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the instant claims 9-11 where the second material is a thermally conductive filler such as metal particles, graphite or talc.

16. Gong discloses a sample preparation chip that includes loading ports and reaction chambers on a substrate where the substrate is made from materials such as glass or PDMS. For claims 9-11, the substrate incorporates a metallic powder filling or metal particles ([0082]) where this powder filling provides the advantage of improved heat conduction within the substrate ([0082]) and demonstrates that the use of a thermally conductive filler within a substrate was an art recognized method for improving the heat conduction within a chip. Therefore, it would have been obvious for one of ordinary skill in the art to employ the filler suggested by Gong within the substrate of Woudenberg with a reasonable expectation of success. The suggestion for doing so at the time would have been in order to improve the conduction of heat through the substrate when the substrate is composed of a material such as plastic ([0082]).

17. With regards to claim 14, Woudenberg discloses an outlet that can serve as a vent and is connected to the detection chambers by a channel (in fluid communication) as was discussed for claim 1. Woudenberg differs from the instant claim in that a plurality of vents is not explicitly disclosed by the reference. However, the use of a plurality of vents is merely duplication of parts that would be obvious for one of ordinary skill in the art to include within Woudenberg in order to obtain the predictable result of quickly removing air or gas from all of the reaction chambers. Furthermore, it is noted that duplication of parts (one vent versus a plurality of vents) with no presentation of a

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new or unexpected result over the prior art has no patentable significance, consult *In re Harza*, 247 F.2d 669, 124 USPQ 378 (CCPA 1960) and MPEP § 2144.04 VI (B).

18. In the alternative, Gong discloses multiple vents (vents 52; [0130]) in the top layer that allow fluid to flow within the various channels. Therefore, it would be obvious for one of ordinary skill in the art to employ the vents suggested by Gong with the substrate of Woudenberg in order to obtain the predictable result of venting gas and air out of the distribution network.

19. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Woudenberg et al. (US 6,126,899) in view of Gong et al. (US 2003/0138941 A1) as applied above and in further view of Pugla et al.(US 2003/0166265 A1).

20. Woudenberg and Gong differ from the instant claim requiring a capillary stop within the channel.

21. Pugla discloses an apparatus for the precise transfer and manipulation of fluids by either centrifugal or capillary forces that includes for claim 15 a plurality of vent channels (vents V1 and V2) and a capillary stop (stop 5; [0034]). The use of a capillary stop is a conventional means for controlling the fluid flow within micro-fluidic channel. In the case of Pugla, the reference uses capillary stop to control the flow of a sample from an inlet reservoir to the reaction chambers and does not explicitly state that the capillary stop is used in conjunction with a vent. However, the problem within the instant application of minimizing leaks from a vent is a well known problem within the art. This has been solved by using hydrophobic coatings within the vent channel, liquid



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impermeable membranes, and channels with a reduced cross-sectional area, weirs and micro-valves. Therefore, it would have been obvious for one of ordinary skill in the art to try the capillary stop of Pugla within the vent channel of Woudenberg and Gong in order to achieve the predictable result of preventing leaks from the vent.

22. Claims 12 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Woudenberg et al. (US 6,126,899) in view of Aylward et al. (US 2005/0064154 A1).

23. With regards to the substrate of claim 12, Woudenberg discloses that the substrate can be made of plastics, polymers and copolymers such as polypropylenes, polystyrene, polyimides and polycarbonates (col. 10 lines 62-64), but differs from the instant claim requiring a substrate made of aromatic polyester, aromatic poly (ester-amide), an aromatic-aliphatic poly (ester-amide), an aromatic polyazomethines or an aromatic polyestercarbonate.

24. Aylward discloses a transparent, invisible conductive grid that includes a flexible substrate. This substrate can be made from a variety of materials such as a cyclic polyolefin or a polyester ([0149]). The preferred polyester is an aromatic polyester such as Arylite ([0149]).

25. The applied reference of Aylward demonstrates that this material was known and art recognized and that the skilled artisan would have been aware of the functions and uses of this substrate at the time of the instant application. Therefore, one of ordinary

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skill in the art would have found it obvious to substitute the substrate material of Aylward for the substrate material of Woudenberg in order to have a biologically inert surface for the sample fluid.

26. For claim 36, Woudenberg discloses the following limitations:

*"a substrate and an optically transparent cover"*: the reference discloses a substrate (substrate 32) and a transparent window or cover where this window is formed of various layers composed of either silica-based glasses, quartz, polycarbonate or an optically transparent plastic layer (col. 5 lines 44-46; col. 11 lines 14-18).

Regarding the structural limitations of the substrate:

*"a first surface"*: The substrate disclosed by Woudenberg includes a first surface as shown in Figure 1B.

*"at least one sample receiving chamber"*: The applied reference includes a sample inlet (inlet 38a) or sample receiving chamber (col. 6 line 6).

*"at least one distributor channel in fluid communication with the [...] sample receiving chamber"*: A distribution network (network 34a) or channel(s) are disclosed by the reference (col. 6 lines 5-6).

*"at least one reaction chamber"*: There are a plurality of detection or reaction chambers (chamber 44a) that branch off the distribution channel (col. 6 lines 6-7) and with regards to the chambers comprising a *"a recess in the first surface"*, the chambers are present within the substrate and are being interpreted as forming a "recess" within the substrate.

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*“at least one inflow channel”*: With regards to the inflow channel, the section of the single flow channel (channel 46a) between the inlet (inlet 38) and the first of the detection chambers (chambers 44a) as shown in Figure 1 is being interpreted as the inflow channel of the instant application.

*“at least one vent”*: Woudenberg discloses a vacuum port (port 40) is in fluid communication with the detection chambers (Fig. 1a) and is fully capable of functioning as a vent. In the alternative, the port can be connected to a three-way valve in order to expose the network to either a vacuum source or a vent (col. 9 lines 45-48).

27. With regards to the substrate of claim 36, Woudenberg discloses that the substrate can be made of plastics, polymers and copolymers such as polypropylenes, polystyrene, polyimides and polycarbonates (col. 10 lines 62-64), but differs from the instant claim requiring a substrate made of aromatic polyester, aromatic poly (ester-amide), an aromatic-aliphatic poly (ester-amide), an aromatic polyazomethines or an aromatic polyestercarbonate.

28. For claim 36, Aylward discloses a transparent, invisible conductive grid that includes a flexible substrate. This substrate can be made from a variety of materials such as a cyclic polyolefin or a polyester ([0149]). The preferred polyester is an aromatic polyester such as Arylite ([0149]).

29. The applied reference of Aylward demonstrates that this material was known and art recognized and that the skilled artisan would have been aware of the functions and uses of this substrate at the time of the instant application. Therefore, one of ordinary

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skill in the art would have found it obvious to substitute the substrate material of Aylward for the substrate material of Woudenberg in order to have a biologically inert surface for the sample fluid.

30. It should be further noted that Woudenberg discloses the claimed invention except for the substrate being made of aromatic polyester, aromatic poly (ester-amide), an aromatic-aliphatic poly (ester-amide), an aromatic polyazomethines or an aromatic polycarbonate. However, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to use aromatic polyester, aromatic poly (ester-amide), an aromatic-aliphatic poly (ester-amide), an aromatic polyazomethines or an aromatic polycarbonate as the substrate, since it has been held to be within the general skill of the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Response to Arguments***

31. Applicant's arguments filed 07/08/2010 have been fully considered but they are not persuasive.

32. In the first three paragraphs on page 5, applicant summarizes the current claim status and the rejection from the previous Office Action.

33. Starting in the fourth paragraph on page 5, applicant traverses the rejection.

34. In the fourth paragraph on page 5, applicant argues that the Woudenberg does not disclose a material having a glass transition greater than 115 degrees C and states that the maximum temperature disclosed by Woudenberg is 95 degrees C. The

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applicant is mischaracterizing the reference here as this temperature is not related to the glass transition of the substrate, but to the annealing temperature during amplification.

35. In the fifth and sixth paragraphs on page 5, applicant argues that the Office Action did not establish that the substrate inherently has the described glass transition and that this can not be established based on probabilities or possibilities. The examiner disagrees with this characterization of the reference as Woudenberg discloses a substrate that can be made of either a silica-based glass or polycarbonate. In the event the substrate is made of polycarbonate, it is well known within the art that polycarbonate has a glass transition temperature greater than 115 degrees C as evidenced by Liu et al.

36. In the first paragraph on page 6, applicant continues this argument, but this argument has already been addressed.

37. Applicant's arguments in the second and third paragraph on page 6 appear to re-iterate the previous argument and have therefore, been addressed.

38. In the fourth paragraph on page 6, applicant argues that Aylward does not cure the deficiencies within Woudenberg. As this argument re-iterates the argument made on page 5, this has already been addressed.

39. Starting on the bottom of page 6 and continuing to page 7, applicant argues that the skilled artisan would not look to the applied reference of Aylward for the material of the substrate and that the references are non-analogous art.

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40. First, “A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton.”KSR, 550 U.S. at \_\_\_\_, 82 USPQ2d at 1397. “[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle.”Id. Office personnel may also take into account “the inferences and creative steps that a person of ordinary skill in the art would employ.”Id. at \_\_\_\_, 82 USPQ2d at 1396.

41. Next, in response to applicant's argument that the skilled artisan would not find it obvious to incorporate the substrate of Aylward into Woudenberg, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

42. In response to applicant's argument that Aylward is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Aylward demonstrates that the materials of the instant claim were known at the time of the instant application and that these materials can be used as substrates or supports.

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43. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

44. Therefore, the rejection will stand.

### ***Conclusion***

45. No claims are allowed.

46. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./  
Examiner, Art Unit 1797

/William H. Beisner/  
Primary Examiner, Art Unit 1797